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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,702	07/05/2001	Robert J. D' Amato	05213-0910 (43170-219505)	8386

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JOHN S. PRATT, ESQ  
KILPATRICK STOCKTON, LLP  
1100 PEACHTREE STREET  
SUITE 2800  
ATLANTA, GA 30309

EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/04/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/899,702

Applicant(s)

D' AMATO ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-4, 7-11 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 15-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 4, 11-14 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

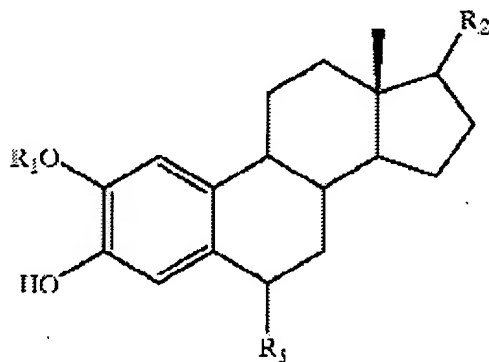
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Acknowledgement is made of the response filed in paper no. 16 dated 3/4/03. Amendments are entered. Claims 1-4 and 7-11, and 13-30 are pending. No claim is allowed. All the art ejections are withdrawn as claims are amended to overcome the rejections. The rejection under 112(1) is maintained for the same reasons as set forth in our previous office action because arguments are not found persuasive. New rejections over the amended claims are as follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lovely et al. (J. Med. Chem. (1996), 39, 1917-1923). See compound 1, 2 and 3 on page 1917 where X can be OH; CH<sub>2</sub>OH; and CH<sub>2</sub>CH<sub>2</sub>OH. These compounds are claimed by the present invention when R<sub>g</sub> is OH; Z'' is CH<sub>2</sub>; Z' is OH; R<sub>a</sub> and R<sub>b</sub> are H and R<sub>a</sub> is R-R<sub>1</sub>.



Claims 1, 2, 3, 4, 11, ~~12~~, 13, 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ram et al. (US Patent 6,136,992). See the

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entire document especially abstract lines 1-59 in col. 2. The reference teaches 2-alkoxy estradiol derivatives that embrace presently claimed invention.

Instant claimed invention differs from the reference in claiming a broader scope. Instant claims are considered obvious when in prior art R3 represents C=N-OH or C=N-O-lower alkyl; R1 is substituted or unsubstituted lower alkyl group; R2 is OH.

It would have been obvious to one skilled in the art at the time of invention to prepare additional beneficial compounds having anticancer activity because prior art teaches such compounds and their specific medicinal uses. One would be motivated to prepare such estradiol derivatives just by selecting any compound taught by the prior art.

The claims as presented are therefore considered obvious to one skilled in the art at the time of invention. Applicant(s) must clearly point out the novelty of the presently claimed invention.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



SABIHA QAZI, PH.D  
PRIMARY EXAMINER